

## REMARKS

In the non-final Office Action all pending claims 1-20 stand rejected.

Herewith Applicants amend XX claims, cancel XXX claims and add no new claims.

Applicants respectfully request entry and favorable consideration of the amendments tendered herewith.

### **Rejections under 35 U.S.C. §102**

**Claims 1, 8, 12, and 14 are rejected as allegedly anticipated under 35 U.S.C. §102(b) by the '341 patent to Hunter et al. (Hunter1).**

**Claims 1, 2, 5, 6 8-12, 14, and 15 are rejected as allegedly anticipated under 35 U.S.C. §102(e) by the '806 published U.S. patent application to Hunter et al. (Hunter2).**

Applicants respectfully traverse the rejections.

For the rejections to stand, *each and every claimed element* must be present in a single reference.

Applicants respectfully point out that Hunter1 and Hunter2 are devoid of any teaching regarding navigation of a distal portion of a medical electrical lead through a portion of a coronary sinus based on differing (i.e., increased) temperature of blood (i.e., exploiting the fact that a temperature variation exists between blood present within the right atrium and blood exiting the coronary sinus).

### **Rejections under 35 U.S.C. §103**

**Claims 16-18 and 20 are rejected as allegedly unpatentable over Hunter2.**

In the Office Action, the Examiner rejected claims 16-18 and 20 under 35 U.S.C. §103(a) as being unpatentable over Hunter2 (solely).

According to the Examiner, Hunter2 discloses the claimed invention *except for* at least a lack of disclosure regarding the right atrium, or that the landmark location is the coronary sinus.

The Examiner concluded, however, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use “this method” since it is used for other cardiac anatomy and as such would be applicable for use in the right atrium and coronary sinus. Applicants respectfully point out that Hunter2 is also devoid of any teaching regarding a temperature variation existing between blood present within the right atrium and blood exiting the coronary sinus.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a prima facie case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a “teaching or suggestion to one of ordinary skill in the art to make the changes that would produce” the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A prima facie case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. “Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: “This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority.” *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the Examiner provided none: no references pertaining to aggregation or averaging

were cited, no official notice was taken, no evidence of any kind was presented. The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. Id. Assertions such as "common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's obligation to make an evidentiary record. Id. at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 ("[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

The Examiner presented no evidence of any suggestion or motivation to modify the Hunter techniques to arrive at the claimed invention. Nor has the Examiner presented any evidence that the recited elements are known in the art. The record consists exclusively of conclusory statements by the Examiner, which are not evidence and which cannot support rejections under 35 U.S.C. § 103.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 38-46 (and 54-52 and 70-78) under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

**Claims 3 and 4 are rejected as allegedly unpatentable over Hunter2 in view of the '148 patent to Lesh et al. (Lesh).**

Applicants repeat the foregoing information about Hunter2 as set forth above and note furthermore that Lesh is also devoid of disclosure regarding insertion of a chronically implanted medical electrical lead.

Indeed, Lesh deals with **ablation** of myocardial tissue and not with implantation of pacing leads and thus teaches away from the present invention.

In point of fact, Lesh specifically claims ablation; to wit:

1. A method for ablation of arrhythmogenic cardiac tissue comprising:
  - selecting a catheter comprising:
    - an elongated flexible body having a proximal end and a distal end,
    - an ultrasound assembly having a transducer located at the distal end of the body,
  - and a tissue ablation means;
  - introducing the distal end of the catheter into a cardiac chamber comprising the arrhythmogenic cardiac tissue to be ablated;
  - using the ultrasound assembly to position the tissue ablation means within an effective range of the arrhythmogenic cardiac tissue to be ablated; and
  - activating the tissue ablation means.

Also, the Abstract of Lesh further emphasizes its focus versus the present invention wherein temperature-based surgical navigation is the focus.

#### **Abstract**

Method and apparatus for ablation of cardiac tissue includes a catheter (2, 60) having an elongated flexible body (6, 64), a tissue characterization assembly including a transducer (34) at the distal end (16) of the body and a tissue ablation assembly having a tissue ablation tip (32) at the distal end of the body. The tissue ablation tip is positioned adjacent the tissue to be ablated using the visualization assembly and then activated.

Thus, it can be readily appreciated that one of skill in the art would not look to Lesh and thus, Lesh is not properly combined with Hunter2 and the ground of rejection should be withdrawn.

**Claims 7, 13, and 19 are rejected as allegedly unpatentable over Hunter2 in view of the '703 patent to Zanelli et al. (Zanelli).**

As noted above, Hunter2 fails to disclose basic elements of the claimed invention (alone) and Zanelli fails to add any substance to Hunter2. In fact, Zanelli fails to even mention "temperature" and does not deal with the claimed subject matter in any meaningful manner.

Thus, the Examiner has failed to lodge a *prima facie* obviousness rejection and the claimed invention should be allowed to pass to timely issuance as U.S. Letters Patent.

### **Conclusion**

Applicants submit that the pending claims are now in condition for allowance and request that a notice of allowance be issued in due course.

If there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

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